

### **REMARKS**

The instant application has Claims 1, 2 and 5-10 pending. The Examiner has provided several rejections regarding these claims that are rebutted in the following order:

- I. Claims 1-2 and 5-10 are rejected under 35 U.S.C. § 112 ¶ 1 as allegedly failing to comply with the written description requirement.
- II. Claims 1-2 and 5-10 are rejected under 35 U.S.C. § 112 ¶ 1 as allegedly failing to comply with the enablement requirement.
- III. Claims 1-2 and 5-10 are rejected under 35 U.S.C. § 112 ¶ 1 as allegedly being indefinite.
- IV. Claims 1, 5-6 and 8-10 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 02/059260 To Tang et al.
- V. Claims 1-2 and 5-6 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by NIH MGC entry: AGENCOURT\_10614895 NIH\_MGC\_127 Homo sapiens cDNA clone IMAGE: 6745305 available October 18, 2002 (GenBank Accession: BU963861, or in the alternative, EST Database Search Result 20080519\_112916\_us-10-578-943-7.rst).
- VI. Claims 8-10 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over NIH MGC entry: AGENCOURT\_10614895 NIH\_MGC\_127 Homo sapiens cDNA clone IMAGE: 6745305 in view of WO 94/01548 To Sibson et al.

**I. The Claims Comply With the Written Description Requirement**

The Examiner asserts that:

The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. Specifically, the independent Claim 1 is drawn to a genus of nucleic acids comprising a sequence at least 80% identical to SEQ ID NO: 15 ...

In this case, the only factor present in the claim is a partial structure ... in the form of a recitation of percent identity.

*Office Action pg 2 ¶ 4.* The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 1 to delete the 80% identity limitation regarding SEQ ID NO: 15. To further provide clarity to Claim 1, the limitation that the nucleic acid encode an IL-32 has been removed, as well as the presence of exons 3, 4, 7, and 8. Claims 2, 5, and 6 are concomitantly canceled. These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application. The Examiner is requested to note that the optional presence of the exons are reclaimed in new dependent Claim 46 and Claim 47.

Further, the Examiner states that:

... only an isolated nucleic acid consisting of the sequence of SEQ ID NO: 3 or an isolated nucleic acid molecule encoding the polypeptide of SEQ ID NO: 7 ... meets the written description provision ...

*Office Action, pg 6.* The Applicants disagree and point out that because the Examiner has found SEQ ID NO: 3 novel the Applicants respectfully request rejoinder of SEQ ID NO: 6 (See, new Claim 45) with SEQ ID NOS: 3 & 15. SEQ ID NO: 3 comprises both SEQ ID NO: 15 (SEQ ID NO: 3's positions 9-117) and SEQ ID NO: 6 (SEQ ID NO: 3's positions 40-303). Further, SEQ ID NOS: 6 and 15 partially overlap and also comprise the GCT alanine codon

represented by nucleotide 63 in SEQ ID NO: 3, that the Examiner points to in establishing the novelty of SEQ ID NO: 3.

The Applicants respectively submit that SEQ ID NO:s 15 and 6 meet the written description requirement. The Examiner is respectfully requested to withdraw the pending rejection.

## **II. The Claims Meet The Enablement Requirement**

The Examiner states that:

... the specification ... does not reasonably provide enablement for an entire genus of functionally equivalent polynucleotides and polypeptides, which incorporate all variants and fragments and with at least 80% ... sequence identity ...

*Office Action, pg 6.* The Applicants believe this rejection to be moot based upon the above claim amendments made for other reasons that remove the partial identity language.

The Applicant's specification provides sufficient guidance for one having ordinary skill in the art to determine the scope of the presently claimed embodiment without undue experimentation. Due to the high level of skill in the art, an ordinary artisan can easily determine if a nucleic acid sequence comprises SEQ ID NO: 15, SEQ ID NO: 3, or SEQ ID NO: 6.

The Examiner is respectfully reminded that "undue experimentation" is not simply related to the number of experiments that need to be performed, provided that they are routine:

The specification is enabling of the claims if "experimentation is ... routine ...

*In re Rasmussen*, 211 USPQ 323, 326 (CCPA 1981). This well settled patent law concept is followed by the USPTO Board of Patent Appeals and Interferences and was recently reaffirmed by the Federal Circuit:

The Board observed that "the mere fact that the experimentation may have been difficult and time consuming does not mandate a conclusion that such experimentation would have been considered to be 'undue' in this art. Indeed, great expenditures of time and effort were ordinary in the field of vaccine preparation." Thus, the Board found the Inglis

applications to be enabling. Reviewing the Board's legal conclusion of enablement, as based on its underlying findings of fact, we cannot say that the Board erred

*Falkner v. Inglis*, 448 F.3d 1357, 79 U.S.P.Q.2D (BNA) 1001 (Fed. Cir. 2006) [emphasis added]. In the present case, the experiments required by one having ordinary skill in the art to determine the sequence of a particular nucleic acid does not entail 'undue experimentation'..

In conclusion, the Examiner has not made a *prima facie* case of enablement because there is no evidence on the record rebutting the Applicant's argument that nucleic acid sequencing is not routine and not well within the ability of one having ordinary skill in the art.

The Examiner is respectfully requested to withdraw the pending rejection.

### **III. The Claims Are Not Indefinite**

The Examiner has rejected Claim 1 because:

The phrase "substantially contiguous" renders the claim indefinite because it is no[t] clear what exactly is encompassed by it. For instance one cannot determine if there are any intervening sequences in between the exons, if the exons are part of the same reading frame or if there are any nucleotides added or deleted in each exon.

and,

... [it] is drawn to a nucleic acid encoding "an" alpha isoform of IL-32 and it is not clear if there are any multiple alpha isoform or if "the" alpha isoform of Seq. Id. No. 7 was the intended meaning.

*Office Action pg 10*. The Applicants disagree as it is believed that Figure 5 presents sufficient information such that one having ordinary skill in the art would be able to interpret the claim term. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 1 to delete any reference to exons 2 and 3 or exons 7 and 8. Further, it should be noted that any recitation that the nucleic acid is "an alpha isoform of IL-32" is also deleted. These deletions are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the

prosecution of this application. Consequently, Claim 1 is now presented as a strict composition claim, without reliance upon any functional language.

The Examiner is respectfully requested to withdraw the pending rejection.

#### **IV. Tang et al. Does Not Anticipate The Claims**

The Examiner states that Claims 1, 5-6 and 8-10 are rejected because Tang et al.:

... teach the Seq. Id. No. 118 which contains a fragment between base pairs 100-207 which is 99.1% identical with the Seq. Id. No.: 15 claimed in the instant Application.

*Office Action pg 11.* The Applicants disagree and submit that the Examiner has overstated the identity between Tang's SEQ ID NO: 118 and Applicant's SEQ ID NO: 15. First, Tang' SEQ ID NO: 118 contains 90 base pairs between position 100 and 207, while Applicants' SEQ ID NO: 15 contains 108 base pairs. Second, the "99.1% identity" only exists when the Examiner refers omits part of the Applicants' claimed sequence (i.e., bases 13 – 30) (i.e., the Examiner is relying upon two separate fragments on which the base the rejection and not a single fragment).. Consequently, there is no contiguous interval of bases which have a 99.1% identity between Tang's SEQ ID NO: 118 and Applicant's SEQ ID NO: 15. As such Tang et al. does not anticipate Applicant's SEQ ID NO: 15.

The Examiner is respectfully requested to withdraw the pending rejection.

#### **V. GenBank Accession Number BU963861 Does Not Anticipate The Claims**

The Examiner states that:

The sequence contains an open reading frame which translated from nucleotide 104, would encode the full length of the IL-32 alpha of Seq. Id No. 7.

*Office Action, pg 12.* The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have canceled Claim 2. This cancellation is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Examiner is respectfully requested to withdraw the pending rejection.

**VI. Claims 8-10 Are Not Obvious Over GenBank Accession Number BU963861 and Sibson et al.**

The Examiner is reminded that *KSR v Teleflex* has not changed basic law regarding obviousness determinations. The USPTO Guidelines admit as such, and provide for the situations wherein obviousness may be found. The Applicants do not believe that the Examiner has met the burden of these guidelines.

Further, the *KSR* holding only cautioned against a strict application of the “teaching-suggestion-motivation test” such that an explicit teaching is not required to be found within the cited applications. Nevertheless, it is still required to: i) establish *some motivation* to combine the references either explicitly or implicitly, and ii) establish a *prima facie* case of obviousness, wherein the prior art reference (or references when combined) must teach or suggest all the claim limitations. The Applicants submit that the Examiner has not made a *prima facie* case of obviousness.

The Examiner relies upon GenBank Accession Number BU963861 for the same reasons the Applicant rebutted in regards to the above anticipation rejection to SEQ ID NO: 7. (See, Section V):

The considerations regarding the Sequence with GenBank Accession: BU963861 were presented supra.

*Office Action, pg. 14.* The Examiner admitted that:

... the BU963861 sequence contains a silent mutation at nucleotide 166 (a “C”) ... The corresponding position in Seq. Id. No.: 3 is nucleotide 63 (a “T”) ...

*Office Action, pg. 12.* As discussed above, SEQ ID NO: 15 also comprises this very same difference when compared to BU963861. Therefore, BU963861 lacks a teaching for SEQ ID NO:15. The same holds true for SEQ ID NO: 6.

Similarly, Sibson et al. also lacks a teaching for SEQ ID NO: 15 or for SEQ ID NO: 6. Nevertheless, the Examiner asserts Sibson et al. because:

Sibson et al. disclose that it is generally useful to place a desired cDNA sequence into an expression vector ...

*Office Action pg 14* [emphasis added]. This rejection basis is inconsistent with the holdings of *KSR*. *KSR* requires an Examiner to provide an explicit analysis to support the obviousness rejection:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents ... To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]jections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

*KSR v Teleflex*, 127 S. Ct. 1727, 1740 (2007) [emphasis added]. This, the Examiner has not done. ‘Articulated reasoning’ requires a plausible discussion that, at a minimum, compares and contrasts the teachings of an asserted reference with the Applicants’ specification.

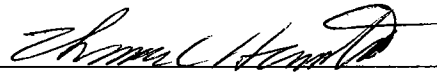
In conclusion, the combination of BU963861 and Sibson et al. thereby fail to teach all the elements of the Applicants amended Claim 1. Consequently, the Examiner has failed to provide a *prima facie* case of obviousness. The Examiner is respectfully requested to withdraw the pending rejection.

### CONCLUSION

The Applicants are fully cognizant of the complexity of the presently contemplated embodiments and thank the Examiner for the careful and deliberate division of the inventions. Nevertheless, the Applicants respectfully request that, once examination begins, the Examiner explicitly identify which Invention/Group/subgenera numbers qualify for Divisional filing practice.

The Applicants believe that the above election is consistent with the Examiner's present Restriction Requirement. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 781-828-9870.

Date: September 15, 2008

By:   
Thomas C. Howerton, J.D., Ph.D.  
Registration No. 48,650

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
781-828-9870